UROGYNECOLOGY

Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

Megan O. Schimpf, MD; David D. Rahn, MD; Thomas L. Wheeler, MD, MSPH; Minita Patel, MD, MS; Amanda B. White, MD; Francisco J. Orejuela, MD; Sherif A. El-Nashar, MBBCh, MS; Rebecca U. Margulies, MD; Jonathan L. Gleason, MD; Sarit O. Aschkenazi, MD; Mamta M. Mamik, MD; Renée M. Ward, MD; Ethan M. Balk, MD, MPH; Vivian W. Sung, MD, MPH; for the Society of Gynecologic Surgeons Systematic Review Group

OBJECTIVE: Understanding the long-term comparative effectiveness of competing surgical repairs is essential as failures after primary interventions for stress urinary incontinence (SUI) may result in a third of women requiring repeat surgery.

STUDY DESIGN: We conducted a systematic review including English-language randomized controlled trials from 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling or Burch urethropexy. When at least 3 randomized controlled trials compared the same surgeries for the same outcome, we performed random effects model metaanalyses to estimate pooled odds ratios (ORs).

RESULTS: For midurethral slings (MUS) vs Burch, metaanalysis of objective cure showed no significant difference (OR, 1.18; 95% confidence interval [CI], 0.73—1.89). Therefore, we suggest either intervention; the decision should balance potential adverse events (AEs) and concomitant surgeries. For women considering pubovaginal sling vs Burch, the evidence favored slings for both subjective and objective cure. We recommend pubovaginal sling to maximize cure outcomes. For pubovaginal slings vs MUS, metaanalysis of subjective cure favored MUS (OR, 0.40; 95% CI, 0.18—0.85). Therefore, we recommend MUS. For obturator slings vs retropubic MUS, metaanalyses for both objective (OR, 1.16; 95% CI, 0.93—1.45) and subjective cure (OR, 1.17; 95% CI, 0.91—1.51) favored retropubic slings but were not significant. Metaanalysis of satisfaction outcomes favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52—1.13). AEs were variable between slings; metaanalysis showed overactive bladder symptoms were more common following retropubic slings (OR, 1.413; 95% CI, 1.01—1.98, $P = .046$). We recommend either retropubic or obturator slings for cure outcomes; the decision should balance AEs. For minislings vs full-length MUS, metaanalyses of objective (OR, 4.16; 95% CI, 2.15—8.05) and subjective (OR, 2.65; 95% CI, 1.36—5.17) cure both significantly favored full-length slings. Therefore, we recommend a full-length MUS.

CONCLUSION: Surgical procedures for SUI differ for success rates and complications, and both should be incorporated into surgical decision-making. Low- to high-quality evidence permitted mostly level-1 recommendations when guidelines were possible.

Key words: Burch urethropexy, midurethral sling, pubovaginal sling, stress urinary incontinence, single-incision sling

Cite this article as: Schimpf MO, Rahn DD, Wheeler TL, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;210:x.ex-x.ex.

From the Division of Gynecology and Urogynecology, Department of Obstetrics and Gynecology, University of Michigan Medical School, Ann Arbor, MI (Dr Schimpf); Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, TX (Dr Rahn); Department of Obstetrics and Gynecology, University of South Carolina School of Medicine Greenville, Greenville, SC (Dr Wheeler); Department of Obstetrics and Gynecology, Kaiser Permanente, Roseville, CA (Dr Patel); Department of Obstetrics and Gynecology, University of Texas Southwestern at Seton Healthcare Family, Austin, TX (Dr White); Department of Obstetrics and Gynecology and Reproductive Sciences, University of Texas Health Science Center at Houston, Houston, TX (Dr Orejuela); Division of Gynecologic Surgery, Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN (Dr El-Nashar); Division of Urogynecology, Department of Obstetrics and Gynecology, Kaiser Permanente, Oakland, CA (Dr Margulies); Division of Urogynecology, Department of Obstetrics and Gynecology, Carilion Clinic, Roanoke, VA (Dr Gleason); Department of Urogynecology, ProHealth Care, Women's Center, Medical College of Wisconsin, Waukesha, WI (Dr Aschkenazi); Icahn School of Medicine at Mount Sinai, Department of Obstetrics and Gynecology, New York, NY (Dr Mamik); Vanderbilt University Medical Center, Department of Obstetrics and Gynecology, Nashville, TN (Dr Ward); Tufts Medical Center, Institute for Clinical Research and Health Policy Studies, Boston, MA (Dr Balk); and Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology, Women and Infants Hospital of Rhode Island and Warren Alpert Medical School of Brown University, Providence, RI (Dr Sung).

Received Aug. 26, 2013; revised Nov. 22, 2013; accepted Jan. 21, 2014.

The Society of Gynecologic Surgeons provided funding for assistance by methods experts in systematic review and for logistic support.

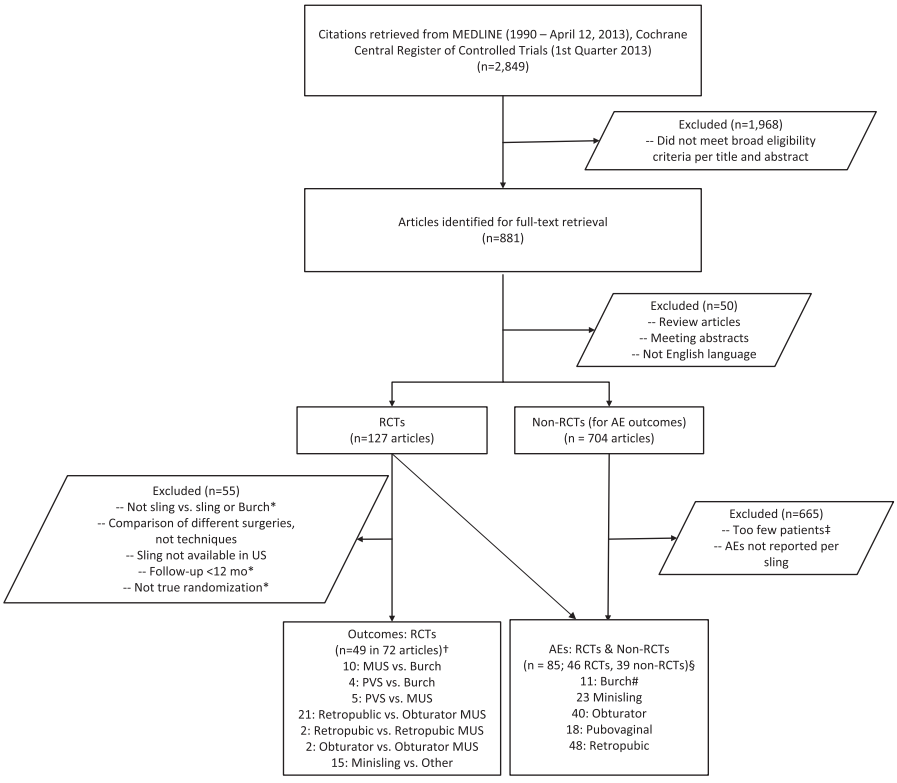
The authors report no conflict of interest.

Presented at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons, Charleston, SC, April 8-10, 2013.

Reprints: Megan O. Schimpf, MD, Obstetrics and Gynecology, Female Pelvic Medicine and Reconstructive Surgery, University of Michigan, L4000 Women's, 1500 E. Medical Center Dr., Ann Arbor, MI 48109. mschimpf@umich.edu.

0002-9378/$36.00 • • http://dx.doi.org/10.1016/j.ajog.2014.01.030

FIGURE 1
Literature flow



PVS, pubovaginal slings.

*These studies were potentially eligible to be included for adverse event (AE) analyses; †Several studies had 3 arms and provided data for multiple comparisons; ‡For noncomparative studies, the following minimum sample size criteria were used: minisling obturator, n ≥120; minisling retropubic, n ≥100; obturator midurethral sling (MUS), n ≥1000; pubovaginal fascial, n ≥300; pubovaginal synthetic, n ≥120; retropubic MUS, n ≥1000; §Several studies reported on ≥2 slings; #Only from randomized controlled trials (RCTs).

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Stress urinary incontinence (SUI), or the involuntary loss of urine with activity such as coughing, laughing, and sneezing, is present in 15-80% of women.[1] Options for treating SUI include physical therapy, pessaries, urethral bulking injections, and surgery. Surgery traditionally consisted of Burch urethropexy or pubovaginal sling. Since 1996, when Ulmsten et al[2] published the initial paper about retropubic tension-free vaginal tape (TVT), the use of synthetic midurethral slings (MUS) has grown to become the most common surgery performed for SUI in women.[3] This type of surgery has evolved to also include options of obturator passage and smaller, single-incision synthetic slings (eg, "minislings").

The decision of which SUI procedure to perform can include suture-only, native tissue, mesh, laparoscopic, open incisions, small incisions, or single-incision surgery. Many studies have compared these options. The primary aim of our work was to utilize systematic review and meta-analysis methodology to compare objective and subjective cure rates in adult women with SUI between these different surgeries. The secondary outcomes were to compare surgical methods by quality-of-life measures, sexual function, and perioperative and adverse event (AE) data.

Materials and Methods

The Society of Gynecologic Surgeons Systematic Review Group includes members with clinical and surgical expertise on female SUI and in the conduct of systematic reviews and guideline development. This project was considered exempt from institutional review board approval.

Data sources and searches

We searched MEDLINE and Cochrane Central Register for Controlled Trials from Jan. 1, 1990 through April 12, 2013 (Figure 1). We excluded older studies because the TVT was not available in the United States prior to this. Search terms included "urinary incontinence," "urgency," "sling," "obturator," "retropubic," "pubovaginal," "vaginal tape," "urologic surgical procedures" (instrumentation or adverse effects), and related terms. The search was limited to comparative studies, cohort studies, and systematic reviews. The search was further limited to human and English-language studies. Meeting abstracts were excluded. Any review articles obtained in this search were excluded after reference lists were reviewed and articles not originally in the search were obtained. Study authors were not contacted.

Twelve reviewers independently double-screened the abstracts using the computerized screening program Abstrackr (Tufts Medical Center, Boston, MA).[4] To establish relevance and consensus among reviewers, all 12 screened and achieved consensus on an initial batch of 300 abstracts. Potentially relevant full-text articles were also independently double-screened by 12 reviewers.

Study selection

For the principal evaluation of outcomes, we included peer-reviewed randomized controlled trials (RCTs) with at least 12 months of follow-up (Table 1). Trials were excluded from outcomes analysis for poor randomization schemes, such as alternate assignment of patients or assignment based on day of the week or birth date. We included RCTs that compared ≥2 sling procedures or a sling procedure to Burch urethropexy performed in adult women for SUI. Studies that compared Burch urethropexy to any other surgery were excluded. Bulking injections were excluded because they are not similar enough to sling surgeries regarding cure, perioperative data, or AEs. When a study included 3 arms, it was analyzed as multiple 2-arm comparisons. For the evaluation of AEs we

TABLE 1
Randomized controlled trials included in systematic review

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
MUS vs Burch												
Bai et al,[9] 2005[a]	B	Retropubic MUS (TVT)	Burch	31	33	12 mo	X			X		
Bandarian et al,[10] 2011	C	Obturator MUS (TOT, unspecified)	Burch	31	31	25 mo mean		X	X	X		
Foote et al,[11] 2006	C	Retropubic MUS (SPARC)	Laparoscopic Burch	49	48	24 mo	X	X	X	X		
Liapis et al,[12] 2002	C	Retropubic MUS (TVT)	Burch	36	35	24 mo	X	X	X	X		
Paraiso et al,[13] 2004[b]	B	Retropubic MUS (TVT)	Laparoscopic Burch	36	36	21 mo	X	X	X	X	X	
Persson et al,[14] 2002	B	Retropubic MUS (TVT)	Laparoscopic Burch	38	33	12 mo	X	X	X	X		
Sivaslioglu et al,[15] 2007	A	Obturator MUS (Safyre T)	Burch	49	51	24 mo	X	X	X	X		
Téllez Martínez-Fornés et al,[16] 2009	B	Retropubic MUS (TVT)	Burch	24	25	36 mo	X	X	X	X	X	
Wang and Chen,[17] 2003	B	Retropubic MUS (TVT)	Burch	49	49	22 mo	X	X	X	X		
Ward et al,[18] 2002[c]	B	Retropubic MUS (TVT)	Burch	169	175	5 y	X		X	X	X	X
PVS vs Burch												
Albo et al,[19] 2007 (SISTEr Trial)[d]	A	PVS (autologous fascia)	Burch	326	329	24 mo	X	X	X	X	X	
Bai et al,[9] 2005[a]	B	PVS (autologous fascia)	Burch	28	33	12 mo	X			X		
Culligan et al,[20] 2003[e]	B	PVS (Gore-Tex)	Burch	17	19	73 mo	X		X	X		
Enzelsberger et al,[21] 1996	C	PVS (dura mater)	Burch	36	36	36 mo	X		X	X		
PVS vs MUS												
Amaro et al,[22] 2009	C	PVS (autologous fascia)	Retropubic MUS (TVT)	21	20	44 mo		X	X	X	X	
Bai et al,[9] 2005[a]	B	PVS (autologous fascia)	Retropubic MUS (TVT)	28	31	12 mo	X			X		
Guerrero et al,[23] 2010[f]	B	PVS (autologous fascia)	Retropubic MUS (TVT)	79	50	12 mo		X	X	X	X	
Sharifiaghdas and Mortazavi,[24] 2008	B	PVS (autologous fascia)	Retropubic MUS (TVT)	52	48	40 mo	X	X	X	X	X	
Tcherniakovsky et al,[25] 2009	C	PVS (autologous fascia)	Obturator MUS (Safyre T)	20	21	12 mo	X		X	X		
Retropubic vs obturator MUS												
Aniuliene,[26] 2009	C	TVT	TVT-O	114	150	12 mo		X	X	X		
Araco et al,[27] 2008	B	TVT	TVT-O	108	100	12 mo	X		X	X	X	
Ballester et al,[28] 2012[g]	B	Retropubic ISTOP	Transobturator ISTOP	42	46	48 mo	X	X	X	X	X	

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TABLE 1
Randomized controlled trials included in systematic review *(continued)*

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Barber et al,[29] 2008[h]	A	TVT	Monarc	88	82	18 mo	X	X	X	X	X	X
Deffieux et al,[30] 2010	A	TVT	TVT-O	75	74	24 mo	X	X	X	X	X	X
El-Hefnawy et al,[31] 2010	C	TVT	Obturator MUS (unspecified)	19	21	20 mo	X	X	X	X		
Freeman et al,[32] 2011	A	TVT	Monarc	93	100	12 mo		X	X	X	X	X
Karateke et al,[33] 2009	A	TVT	TVT-O	83	84	14 mo	X	X	X	X	X	
Krofta et al,[34] 2010	A	TVT	TVT-O	149	151	12 mo	X	X	X	X	X	X
Liapis et al,[35] 2006	C	TVT	TVT-O	46	43	12 mo	X	X	X	X		
Richter et al,[1] 2010 (TOMUS Trial)[i]	A	TVT	Obturator MUS (TVT-O or Monarc)	298	299	24 mo	X	X	X	X	X	X
Rinne et al,[36] 2008[j]	A	TVT	TVT-O	136	131	36 mo	X	X	X	X	X	
Ross et al,[37] 2009	B	Retropubic MUS (Advantage)	Obturator MUS (Obtryx)	105	94	12 mo	X	X	X	X	X	X
Scheiner et al,[38] 2012[k]	B	TVT	Monarc	80	40	12 mo	X	X	X	X	X	X
Scheiner et al,[38] 2012[k]	B	TVT	TVT-O	80	40	12 mo	X	X	X	X	X	X
Schierlitz et al,[39] 2008[l]	B	TVT	Monarc	82	82	36 mo	X	X	X	X		X
Teo et al,[40] 2011	B	TVT	TVT-O	66	61	12 mo	X	X	X	X	X	
Wang F et al,[41] 2010	A	TVT	Obturator MUS (out-to-in)	70	70	12 mo	X	X	X	X	X	
Wang W et al,[42] 2009	B	TVT	TVT-O	160	155	36 mo	X		X	X		
Wang YJ et al,[43] 2011[m]	B	TVT	TVT-O	32	36	12 mo	X		X	X		
Zullo et al,[44] 2007[n]	B	TVT	TVT-O	35	37	5 y	X	X	X	X	X	X
Retropubic MUS vs retropubic MUS												
Andonian et al,[45] 2005	B	SPARC	TVT	41	43	12 mo	X	X	X	X		
Tseng et al,[46] 2005	B	SPARC	TVT	31	31	24 mo	X		X	X		
Obturator MUS vs obturator MUS												
Abdel-Fattah et al,[47] 2010 (E-TOT Trial)[o]	B	ARIS TOT (out-to-in)	TVT-O (in-to-out)	171	170	12 mo	X	X		X	X	X
Scheiner et al,[38] 2012[k]	B	Monarc	TVT-O	40	40	12 mo	X	X	X	X	X	

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(continued)

TABLE 1
Randomized controlled trials included in systematic review *(continued)*

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Minisling vs any other sling												
Andrada Hamer et al,[48] 2013	B	TVT-Secur H	TVT	64	69	12 mo	X	X	X	X		
Barber et al,[49] 2012	A	TVT-Secur U	TVT	136	127	12 mo	X	X	X	X	X	X
Hinoul et al,[50] 2011	A	TVT-Secur H	TVT-O	97	98	12 mo	X	X	X	X	X	
Hota et al,[51] 2012	A	TVT-O	TVT-Secur	44	42	12 mo	X	X	X	X	X	
Kim et al,[52] 2010	B	TVT-Secur U	TVT-Secur H	53	62	12 mo	X	X	X	X	X	X
Lee et al,[53] 2010	A	TVT-Secur U	TVT-Secur H	165	165	12 mo	X	X	X	X	X	X
Masata et al,[54] 2012[p]	A	TVT-Secur U	TVT-O	65	68	24 mo	X	X	X	X	X	
Masata et al,[54] 2012[p]	A	TVT-Secur H	TVT-O	64	68	24 mo	X	X	X	X	X	
Masata et al,[54] 2012[p]	A	TVT-Secur U	TVT-Secur H	65	64	24 mo	X	X	X	X	X	
Oliveira et al,[55] 2011[q]	C	TVT-Secur H	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al,[55] 2011[q]	C	MiniArc	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al,[55] 2011[q]	C	TVT-Secur H	MiniArc	30	30	12 mo	X		X	X		
Tommaselli et al,[56] 2010	B	TVT-Secur H	TVT-O	42	42	12 mo	X		X	X	X	
Wang YJ et al,[43] 2011[m]	B	TVT-Secur	TVT	34	32	12 mo	X		X	X		
Wang YJ et al,[43] 2011[m]	B	TVT-Secur	TVT-O	34	36	12 mo	X		X	X		

Advantage; Boston Scientific Corp., Natick, MA; Gore-Tex; Gore Medical, Flagstaff, AZ; ISTOP, CL Medical, Winchester, MA; MiniArc; AMS, Minnetonka, MN; Monarc; AMS; Obtryx; Boston Scientific Corp.; Safyre; Promedon, Cordoba, Argentina; SPARC; AMS; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur, Ethicon Gynecare.

AE, adverse event; *MUS*, midurethral sling; *OC*, objective cure; *Po*, perioperative outcomes; *PVS*, pubovaginal sling; *QoL*, Life-of-life outcomes; *SC*, subjective cure; *SF*, sexual function outcomes; *TOMUS*, Trial of Midurethral Slings; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

[a] 3-Arm trial comparing PVS (autologous fascia) vs TVT vs Burch; [b] Jelovsek et al[59] 2008; [c] Ward et al[60] 2004 and Ward et al[61] 2008; [d] Tennstedt et al[62] 2005, Tennstedt et al[63] 2008, Chai et al[64] 2009, Kraus et al[65] 2011, Brubaker et al[66] 2012; [e] Sand et al[67] 2000; [f] Trial also included PVS (Pelvichol) arm (n = 72) that was not included as Pelvichol is off market; [g] Daraï et al[68] 2007 and David-Montefiore et al[69] 2006; [h] Barber et al[70] 2008; [i] Albo[71] 2008, Brubaker et al[72] 2011, Zyczynski et al[73] 2012, Albo et al[3] 2012; [j] Laurikainen et al[74] 2007 and Palva et al[75] 2010; [k] 3-Arm trial comparing Monarc vs TVT vs TVT-O; [l] Schierlitz et al[76] 2012 and De Souza et al[77] 2012; [m] 3-Arm trial comparing TVT-Secur vs TVT vs TVT-O; [n] Angioli et al[78] 2010; [o] Abdel-Fattah et al[79] 2010 and Abdel-Fattah et al[80] 2012; [p] 3-Arm trial comparing TVT-Secur H vs TVT-Secur U vs TVT-O; [q] 3-Arm trial comparing TVT-O vs TVT-Secur H vs MiniArc; [r] A (good), B (fair), C (poor).

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TABLE 2
Categorization of outcomes analyzed from randomized controlled trials

Outcome category of interest	Specific outcomes collected
Objective cure	Cough stress test
	Pad testing
	Urodynamic stress incontinence
	Voiding diary data
Subjective cure	Sandvik Incontinence Severity Index
	International Consultation on Incontinence Questionnaire (ICIQ)
	Patient Global Impression of Improvement (PGI-I)
	Pelvic Floor Distress Inventory (PFDI)
	Urinary Distress Inventory (UDI)
	Bristol female lower urinary tract symptom (BFLUTS)
	Measures such as "better" or "satisfied"
	"Would recommend to a friend"
	Met expectations
Perioperative outcomes	Estimated blood loss, time to return to normal activity/work, operative time, hospital time, length of stay, length of use of catheter, pain
Quality of life or satisfaction	Kings Health Questionnaire (KHQ)
	Measures of activities of daily living
	Urinary Incontinence Quality-of-life Scale (I-QOL)
	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Floor Impact Questionnaire/Incontinence Impact Questionnaire (PFIQ/IIQ)
	International Consultation on Incontinence Questionnaire (ICIQ)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
Sexual function	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
	Dyspareunia
	"Return to normal sex life"
Adverse events	Table 3

IUGA, International Urogynecology Association.

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also included trials excluded from RCT analysis, nonrandomized comparative studies, and cohort (pre-post) studies of any follow-up duration. Because of the volume of these studies, sample size limitations were placed to restrict the number of studies to only those with the most patients and therefore highest potential for identifying a complication (Figure 1). Studies included for AEs had to evaluate at least 1 sling type, and information about any other comparator surgery was not collected. Sling types of interest included MUS (retropubic, obturator), pubovaginal slings at the bladder neck (biologic, synthetic, or autologous), and minislings. All studies had to report results for cohorts (or study arms) of women who all received the same sling type (or Burch urethropexy); studies that combined women who received different sling types in their analyses were excluded. Studies that examined various aspects of surgical technique, anesthesia, or surgeon training were excluded if the same type of sling was used in each arm. Data were excluded if the surgical product used was not available in the United States as of April 2013.

Outcomes of interest from RCTs fell into 6 categories: objective cure, subjective cure, perioperative outcomes, quality of life or satisfaction, sexual function, and AEs (Table 2). Studies with nonrandomized designs were included only for AEs. Information on cost was not collected.

Data extraction and quality assessment

Data were extracted by 1 of 12 reviewers using a standard data extraction form and confirmed by another; discrepancies were resolved by consensus. We extracted data on study characteristics, participant characteristics, funding source, details on the interventions, length of follow-up, outcomes of interest measured, and how these outcomes were assessed. After data extraction, the lead reviewer and methodologist categorized all outcomes extracted from the RCTs into the 6 outcome categories listed above. Two reviewers also categorized all AEs into 22 categories as listed in Table 3. The underlying data, together with additional extracted information, are accessible online at http://srdr.ahrq.gov/ in the project Sling surgery for stress urinary incontinence in women: Society of Gynecologic Surgeons 2013.

We assessed the methodological quality of each RCT using predefined criteria from a 3-category system modified from the Agency for Healthcare Research and Quality.[5] Studies were graded as good (A), fair (B), or poor (C)

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117]

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Estimated blood loss >200 mL					
Obturator	4	0.22% (0.03–1.59%)	1	448	0.00–1.79%
Minisling	3	1.1% (0.5–1.9%)	10	888	0.00–3.68%
Retropubic	4	1.5% (1.0–2.1%)	33	2071	0.21–4.76%
Transfusion					
Burch	3	0.00% (0.00–7.73%)	0	105	0.00–0.00%
Obturator	6	0.17% (0.02–1.22%)	1	584	0.00–0.40%
Retropubic	13	0.40% (0.28–0.55%)	31	8105	0.00–4.00%
Minisling	5	0.51% (0.23–1.14%)	6	1177	0.00–0.74%
Pubovaginal	5	1.9% (0.9–3.2%)	10	515	0.00–5.17%
Hematoma					
Obturator	18	0.59% (0.35–0.89%)	17	2995	0.00–2.41%
Retropubic	25	0.88% (0.74–1.0%)	184	15,950	0.00–16.13%
Minisling	2	0.85% (0.21–3.44%)	2	236	0.74–1.00%
Burch	4	1.4% (0.6–2.6%)	8	542	0.00–5.71%
Pubovaginal	5	2.2% (1.2–3.4%)	14	677	0.00–5.17%
Dyspareunia					
Retropubic	2	0.00% (0.01–1.64%)	0	488	0.00–0.00%
Obturator	6	0.16% (0.02–1.14%)	1	624	0.00–0.40%
Minisling	11	0.74% (0.40–1.2%)	19	1809	0.00–6.49%
Pubovaginal	5	0.99% (0.39–1.9%)	8	696	0.00–2.63%
Return to operating room for erosion					
Burch	2	0.28% (0.04–2.03%)	1	352	0.00–0.30%
Minisling	3	1.4% (0.5–2.8%)	5	399	0.53–2.86%
Pubovaginal	5	1.6% (0.8–2.7%)	16	640	0.00–12.50%
Retropubic	12	1.9% (1.0–3.0%)	13	703	0.00–6.45%
Obturator	7	2.7% (1.5–4.3%)	14	518	0.00–8.24%
Exposure					
Burch	4	0.00% (0.02–6.22%)	0	130	0.00–0.00%
Retropubic	29	1.4% (1.1–1.7%)	84	5684	0.00–12.90%
Minisling	19	2.0% (1.5–2.6%)	61	2408	0.00–19.05%
Obturator	31	2.2% (1.7–2.7%)	66	3253	0.00–10.00%
Pubovaginal	10	5.4% (4.0–7.0%)	48	851	0.00–15.52%
Wound infection					
Minisling	3	0.31% (0.05–0.80%)	2	852	0.00–1.04%
Obturator	14	0.74% (0.43–1.1%)	14	2348	0.00–2.11%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Retropubic	13	0.75% (0.54–0.98%)	43	5781	0.00–13.04%
Pubovaginal	3	2.6% (0.8–5.4%)	4	174	0.85–5.56%
Burch	5	7.0% (4.3–10%)	17	269	3.13–9.68%
Urinary tract infection					
Minisling	13	3.6% (2.8–4.6%)	72	1762	0.74–18.33%
Pubovaginal	4	4.2% (2.5–6.3%)	21	420	1.84–18.75%
Obturator	21	4.3% (3.4–5.2%)	88	1826	0.00–16.79%
Burch	7	5.9% (4.2–7.9%)	55	648	0.00–31.51%
Retropubic	21	11.0% (9.7–11%)	718	6286	0.00–23.33%
Bowel injury					
Obturator	5	0.00% (0.00–1.96%)	0	410	0.00–0.00%
Retropubic	7	0.34% (0.09–1.36%)	2	594	0.00–1.57%
Minisling	1	0.74% (0.10–5.30%)	1	136	0.74–0.74%
Burch	1	3.13% (0.44–23.63%)	1	32	3.13–3.13%
Nerve injury					
Minisling	1	0.00% (0.02–5.95%)	0	136	0.00–0.00%
Retropubic	4	0.06% (0.01–0.43%)	1	1642	0.00–0.07%
Obturator	3	0.61% (0.09–4.36%)	1	165	0.00–1.72%
Ureteral injury					
Retropubic	1	0.00% (0.00–9.25%)	0	88	0.00–0.00%
Pubovaginal	4	0.18% (0.03–1.26%)	1	567	0.00–1.28%
Burch	1	0.61% (0.15–2.46%)	2	329	0.61–0.61%
Obturator	1	1.22% (0.17–8.87%)	1	82	1.22–1.22%
Vascular injury					
Obturator	2	0.00% (0.00–6.75%)	0	120	0.00–0.00%
Retropubic	4	0.08% (0.04–0.18%)	6	7149	0.00–0.09%
Overactive bladder/urgency					
Burch	3	4.3% (2.5–6.5%)	17	387	2.86–21.74%
Obturator	8	5.3% (4.2–6.5%)	106	1485	0.00–34.53%
Minisling	11	5.4% (4.4–6.5%)	103	1769	2.22–21.00%
Retropubic	15	6.9% (6.0–7.7%)	374	3486	0.76–45.00%
Pubovaginal	5	8.6% (6.5–11%)	55	558	3.37–38.10%
Retention lasting <6 wk postoperatively					
Minisling	13	2.1% (1.5–2.8%)	36	1778	0.00–5.88%
Obturator	17	2.3% (1.8–3.0%)	70	2629	0.00–10.00%
Retropubic	18	3.1% (2.7–3.5%)	248	7127	0.00–21.74%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Pubovaginal	10	12% (10.2–14%)	158	1053	3.03–81.97%
Burch	5	17% (13–21%)	55	288	0.00–32.88%
Retention lasting >6 wk postoperatively					
Obturator	6	2.4% (1.4–3.6%)	70	2629	0.00–10.00%
Retropubic	9	2.7% (2.1–3.4%)	248	7127	0.00–21.74%
Minisling	2	3.3% (1.6–5.7%)	36	1778	0.00–5.88%
Pubovaginal	6	7.5% (5.4–10%)	158	1053	3.03–81.97%
Burch	4	7.6% (4.7–11%)	55	288	0.00–32.88%
Return to operating room for urinary retention					
Burch	4	0.00% (0.00–1.54%)	0	522	0.00–0.00%
Obturator	22	1.1% (0.7–1.5%)	23	2342	0.00–6.67%
Retropubic	21	1.2% (0.9–1.7%)	48	3103	0.00–24.00%
Minisling	12	1.9% (1.2–2.9%)	16	970	0.00–5.00%
Pubovaginal	15	3.0% (2.3–3.9%)	57	1667	0.00–7.69%
Groin pain					
Pubovaginal	2	0.34% (0.09–1.36%)	2	591	0.00–0.61%
Minisling	12	0.62% (0.30–1.1%)	14	1619	0.00–5.26%
Burch	2	1.10% (0.42–2.98%)	4	364	0.00–11.43%
Retropubic	12	1.5% (1.0–2.1%)	29	1811	0.00–5.56%
Obturator	17	6.5% (5.3–7.7%)	128	1594	0.00–36.67%
Leg pain					
Retropubic	4	0.62% (0.16–2.51%)	2	322	0.00–1.69%
Minisling	4	1.6% (0.5–3.2%)	4	337	0.00–2.63%
Obturator	7	16% (13–19%)	112	649	3.66–60.87%
Bladder perforation					
Obturator	32	0.70% (0.46–0.98%)	22	4000	0.00–4.76%
Minisling	6	0.85% (0.40–1.5%)	12	1138	0.00–4.41%
Pubovaginal	14	2.3% (1.5–3.3%)	23	1069	0.00–5.56%
Burch	10	2.8% (1.7–4.1%)	19	753	0.00–6.25%
Retropubic	41	3.6% (3.3–3.9%)	420	11,390	0.00–24.39%
Urethral perforation					
Burch	1	0.00% (0.00–34.04%)	0	25	0.00–0.00%
Obturator	7	0.20% (0.05–0.80%)	2	1013	0.00–1.72%
Retropubic	8	0.41% (0.19–0.72%)	17	2211	0.00–5.37%
Minisling	1	2.70% (0.38–20.26%)	1	37	2.70–2.70%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Vaginal perforation					
Pubovaginal	1	0.00% (0.00–2.46%)	0	326	0.00–0.00%
Burch	2	0.21% (0.03–1.50%)	1	475	0.00–0.30%
Retropubic	12	0.73% (0.40–1.2%)	19	1892	0.00–15.00%
Minisling	10	1.3% (0.8–1.9%)	20	1538	0.00–4.84%
Obturator	20	2.8% (2.2–3.5%)	82	2498	0.00–10.87%
Deep vein thrombosis					
Obturator	2	0.00% (0.00–12.03%)	0	68	0.00–0.00%
Retropubic	3	0.06% (0.01–0.43%)	1	1660	0.00–0.07%
Pubovaginal	4	0.35% (0.09–1.42%)	2	567	0.00–1.28%
Burch	3	0.58% (0.11–1.4%)	4	506	0.00–3.23%

AE, adverse event; *CI*, confidence interval.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

quality based on the likelihood of biases and completeness of reporting. Grades for different outcomes could vary within the same study.

Data synthesis and analysis

We were able to identify comparisons for MUS vs Burch, pubovaginal slings vs Burch, pubovaginal slings vs MUS, retropubic MUS vs obturator MUS, retropubic MUS vs retropubic MUS (based on route of passage), obturator MUS vs obturator MUS (based on route of passage), and minisling vs other sling. When at least 3 RCTs compared the same surgeries for the same outcomes and provided adequate data for metaanalysis (including for AEs), we performed random effects model metaanalyses to estimate pooled odds ratios (ORs). We included data from the time point closest to 12 months' follow-up that were reported. For objective cure, studies used cough stress test, pad test, or both methods. Across studies, we treated the different methods as equivalent (ie, we included both methods in the metaanalyses), but when a single study reported both methods, we preferentially chose stress test over pad test or a combined outcome (both pad and stress tests). When at least 3 studies (pre-post, nonrandomized comparative, or RCT) reported the same AE for the same sling type, we performed random effects model metaanalyses of the arcsine transformed proportion of women with the outcome.[6] The arcsine transformed proportion was used to minimize bias due to the nonnormal distribution when proportions are close to 0. However, when the total number of events was <3 or metaanalysis gave an implausible summary estimate, the exact proportion and confidence interval (CI) were calculated for the total number of events and women at risk.[7] These absolute rates of AEs are compared qualitatively between procedures, and all data are presented in Table 3.

For each comparison of different sling types (or vs Burch), we generated an evidence profile by grading the quality of evidence for each outcome according to the Grades for Recommendation, Assessment, Development, and Evaluation system. The process considered the methodological quality, consistency of results across studies, directness of the evidence, and imprecision or sparseness of evidence to determine an overall quality of evidence. Four quality rating categories were possible: high (A), moderate (B), low (C), and very low/insufficient (D).[8] Evidence profiles for the reviewed studies are in the Appendix.

We developed clinical practice guideline statements incorporating the balance between benefits and harms of the compared interventions when the data were sufficient to support these statements. Each guideline statement was assigned an overall level of strength of the recommendation (1 = strong, 2 = weak) based on the quality of the supporting evidence and the size of the net benefit. The strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm. The wording and its implications for patients, physicians, and policymakers are detailed in Table 4.

We presented our findings at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons in April 2013 in Charleston, SC. A link to the guidelines and manuscript was then e-mailed to the entire membership for review and vetting in August 2013 prior to submission for publication.

Results

The MEDLINE search identified 2849 abstracts, of which we retrieved 881

TABLE 4
Society for Gynecologic Surgeons Systematic Review Group sling surgery for stress urinary incontinence in women, clinical practice guidelines

Midurethral sling vs Burch (open or laparoscopic)

For women considering midurethral slings or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure and that decision be based on: (1) which adverse events are of greatest concern to patient; and (2) any other planned concomitant surgeries (vaginal vs abdominal route). (1A)

- Midurethral slings may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas. (1C)
- Burch procedures may result in lower rates of return to operating room for retention, erosion, overactive bladder symptoms, and groin pain. (1C)

Pubovaginal sling vs Burch

For women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes. (1A)

- Burch procedure results in lower rates of erosion, overactive bladder symptoms, and retention requiring reoperation. (1C)
- Pubovaginal slings result in lower rates of wound infection, bladder/vaginal perforation, and bowel injury. (1C)

Pubovaginal sling (biologic and synthetic) vs midurethral sling (only TVT was studied)

For women considering pubovaginal or midurethral sling for treatment of SUI, we recommend midurethral sling for better subjective cure outcomes. (2C)

- Midurethral slings may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay. (2D)
- Pubovaginal slings may result in lower rates of adverse events such as urinary tract infection and vaginal perforation. (2D)

Retropubic vs obturator midurethral slings

For women considering retropubic or transobturator midurethral sling, we recommend either intervention for objective and subjective cure and that decision be based on which adverse events are of greatest concern to patient. (1A)

- Retropubic slings result in lower rates of sling erosion, need to return to operating room for treatment of sling erosion, groin/leg pain, and vaginal perforation. (1D)
- Transobturator midurethral slings result in shorter operative time, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less overactive bladder symptoms. (1D)

Obturator vs obturator or retropubic vs retropubic midurethral slings

There is insufficient evidence to provide recommendation for choosing among specific obturator or retropubic slings.

Minisling (TVT-Secur U/H position and MiniArc studied) vs other sling (TVT and TVT-O studied)

For women considering minislings (specifically TVT-Secur in H or U configuration) compared to traditional midurethral slings for treatment of SUI, we recommend traditional midurethral sling to maximize cure rates. (1A)

- Route of traditional midurethral sling that would be performed is important consideration in regard to adverse events compared with minislings. For example, minislings have similar rates of postoperative overactive bladder symptoms compared with obturator slings, but lower rates compared with retropubic slings. Exposure of sling postoperatively is similar between obturator slings and minislings, but retropubic slings have lower rates than both other types. (1D)
- Dyspareunia is more common with minisling than either retropubic or obturator sling, but absolute rates are low for all types of slings. (1D)

MiniArc; AMS, Minnetonka, MN; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur; Ethicon Gynecare.

SUI, stress urinary incontinence; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

full-text papers that were further assessed in detail (Figure 1). This process resulted in 127 papers detailing RCTs (Table 1), from which there were 49 unique, eligible trials. There were also 704 additional papers reflecting other study designs, which were considered for AE data (Table 3). After limiting the non-RCT papers to those with the largest number of patients, we included 39 of those studies in addition to collecting AE information from RCTs (Table 3).

We categorized the trials into 6 comparisons, which are discussed in detail below and in Table 1.

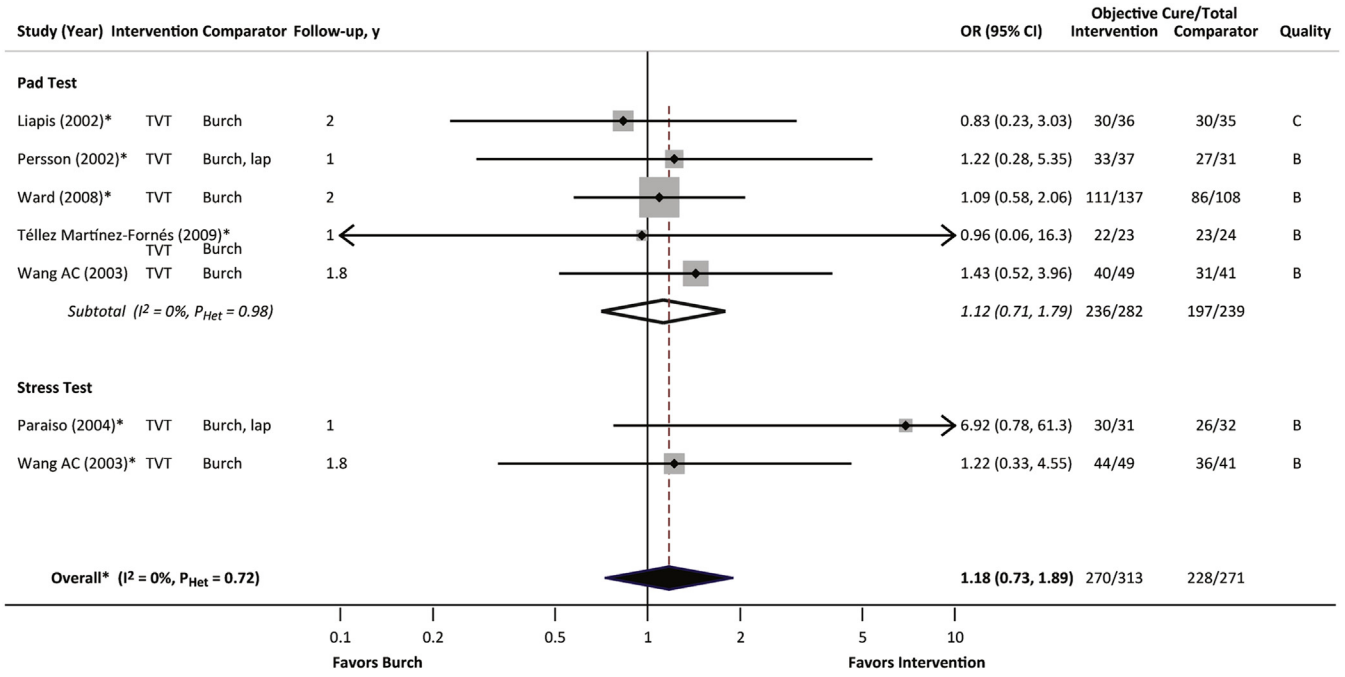
MUS vs Burch urethropexy

There were 10 RCTs for this comparison with overall moderate quality of evidence (Supplementary Table 1).[9-18] Two studies examined obturator MUS,[10,15] while the remaining analyzed a retropubic sling vs Burch urethropexy, which was performed via laparotomy except in 3 studies that analyzed laparoscopic Burch surgery.[11,13,14] There were no studies comparing minislings to Burch urethropexy.

The evidence reviewed did not support a difference between the 2 surgeries with regard to objective cure, subjective cure, quality-of-life, or sexual function outcomes. While 8 studies provided data about cure outcomes, there were fewer studies evaluating quality of life[13,16,18] and sexual function.[18]

Metaanalysis of objective cure did not show a significant difference for sling

FIGURE 2
Metaanalysis for objective cure: MUS vs Burch urethropexy



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

compared to Burch (OR, 1.18; 95% CI, 0.73–1.89) (Figure 2). The 6 RCTs that met inclusion for this outcome analyzed TVT vs Burch, which was performed open or laparoscopically.

For subjective cure, the metaanalysis included retropubic slings (all TVT) and obturator slings (unspecified obturator sling or Safyre T; Promedon, Cordoba, Argentina) (Figure 3). The pooled OR for all analyses showed no significant difference but favored slings compared to Burch (OR, 1.12; 95% CI, 0.79–1.60). Similar results were seen for metaanalyses of retropubic and obturator slings compared individually to the Burch procedure (Figure 3).

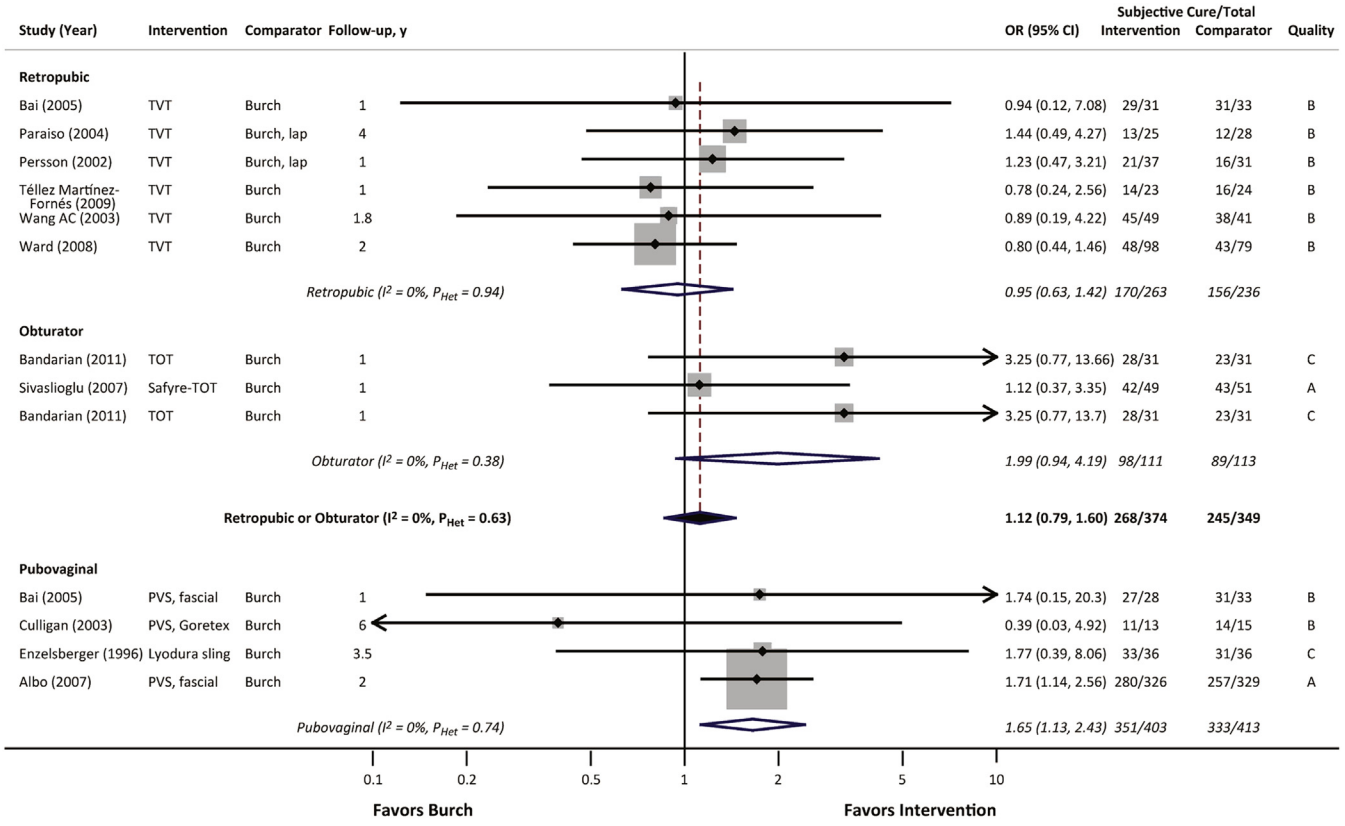
Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Analysis of perioperative and AE data for the absolute rates of complications per type of surgery showed that MUS may result in lower rates of perioperative AEs such as postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas (Appendix and Table 3). Burch procedures may result in lower rates of longer-term AEs such as return to the operating room for retention or erosion, overactive bladder (OAB) symptoms, and groin pain (Table 3). Metaanalysis of AE outcomes that were similar across studies showed no significant difference among these procedures for postoperative OAB symptoms, return to the operating room for erosion, and return to the operating room for retention. Interpretation of these rates is also dependent on the route of the MUS (obturator vs retropubic) that would be chosen, although more studies were available using retropubic slings for this comparison, weighting our analysis.

In summary, for women considering MUS or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure, with the decision based on AEs and other planned concomitant surgeries (vaginal vs abdominal route) (Table 4).

Pubovaginal slings vs Burch urethropexy

There were 4 RCTs for this comparison with an overall high quality of evidence (Supplementary Table 2).[9,19-21] The pubovaginal slings in these studies were composed of autologous fascia, Gore-Tex (Gore Medical, Flagstaff, AZ), or human dura mater.[9,19-21] The data for this grouping included the SISTEr trial, a high-quality, multicenter network trial with 655 subjects investigating autologous pubovaginal slings compared to Burch surgery (Table 1).[19] No studies reported sexual function data and only 1 reported quality-of-life outcomes.[19] The evidence favored sling procedures compared to Burch for subjective and objective cure outcomes.

FIGURE 3
Metaanalysis for subjective cure: slings vs Burch urethropexy



Forest plots subdivided by slings being compared with Burch urethropexy. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

There was an inadequate number of studies to support a metaanalysis of objective cure. Subjective cure outcome metaanalysis favored pubovaginal sling compared to Burch (OR, 1.65; 95% CI, 1.13−2.43) (Figure 3).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Looking at absolute rates of AEs per procedure, a Burch procedure results in lower rates of OAB symptoms, transfusion, hematomas, and return to the operating room for retention or erosion. Pubovaginal slings result in lower rates of wound infection, groin pain, urinary tract infection, and bladder/vaginal perforation. Metaanalysis of AE information showed no significant difference between the 2 surgeries for postoperative OAB symptoms and return to the operating room for erosion. There was a greater risk of return to the operating room for retention with the pubovaginal sling in the 2 studies that could be combined for this question (OR, 14.9; 95% CI, 1.35−165.15; $P = .028$).

In summary, for women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes (Table 4).

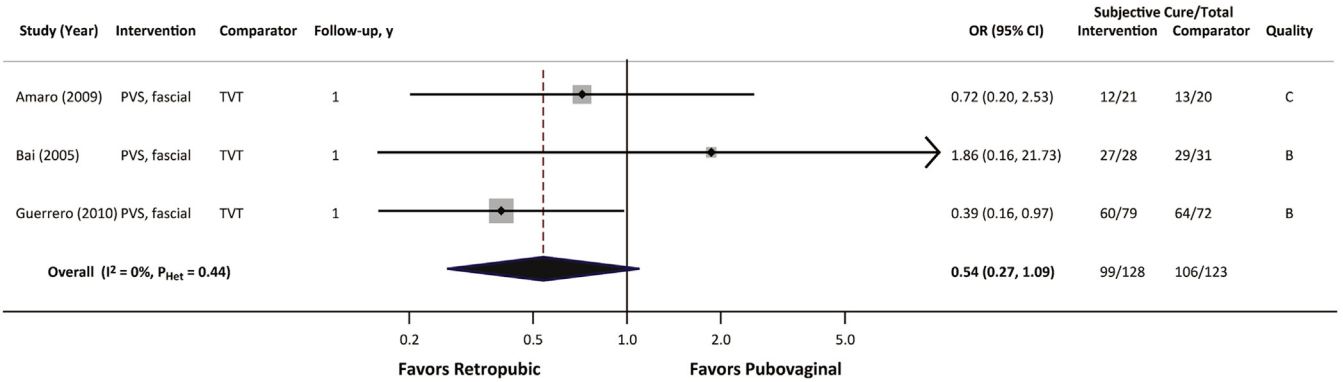
Pubovaginal slings vs MUS

There were 5 RCTs for this grouping and the evidence was overall of low quality (Supplementary Table 3).[9,22-25] The only MUS included in these studies was a retropubic TVT sling. There are no RCTs comparing pubovaginal slings to obturator MUS or minislings. No studies reported sexual function data. Review of the available data did not support a difference between procedures for either cure outcome.

Metaanalysis of data for subjective cure outcomes favors placement of MUS compared to pubovaginal slings (OR, 0.40; 95% CI, 0.18−0.85) (Figure 4). There were inadequate studies to support a metaanalysis for objective cure. Metaanalysis for the satisfaction outcome was also not possible due to a limited number of studies.

Comparing absolute complication rates for the surgeries in general, MUS resulted in lower rates of operating room time, blood loss, transfusion, wound infection, retention, OAB symptoms, and hospital stay (Appendix and Table 3). Interpretation of these rates is also dependent on the route of MUS (obturator vs retropubic) that would be chosen. Pubovaginal slings result in

FIGURE 4
Metaanalysis for subjective cure: pubovaginal vs MUS



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

lower rates of urinary tract infection and vaginal perforation than either route of MUS (Table 3). Metaanalysis of AE information showed no significant difference between these surgeries for postoperative OAB symptoms, return to the operating room for retention, or return to the operating room for erosion.

Driven by the metaanalysis information, for women considering a pubovaginal sling or MUS for treatment of SUI, we recommend MUS for better subjective cure (Table 4).

Retropubic MUS vs obturator MUS

This comparison had the most studies with 21 RCTs with large numbers of patients enrolled (Supplementary Table 4).[1,26-44] The quality of evidence was high, including Trial of Midurethral Slings (TOMUS), a high-quality multicenter network trial with 597 participants.[1] The evidence did not show a difference for objective or subjective cure outcomes between the 2 slings. Quality-of-life and sexual function outcomes were also similar between the 2 procedures.

Metaanalysis of objective cure data favored retropubic slings but was not significant (OR, 1.18; 95% CI, 0.95−1.47) (Figure 5). The retropubic sling studied was a TVT in all studies in the metaanalysis.

Similarly, for subjective cure, metaanalysis favored retropubic slings (OR, 1.17; 95% CI, 0.91−1.51) but was not significant (Figure 6). Again, the retropubic sling for included studies was always a TVT while the obturator slings included a variety of slings and routes of passages.

Four studies were included in a metaanalysis of satisfaction outcomes (Figure 7), which favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52−1.13).

AE and perioperative outcome data were highly variable by each outcome and did not provide a consistent direction when examined by absolute rates of complications for each surgery (Appendix and Table 3). Retropubic slings result in lower absolute rates of sling erosion, need to return to the operating room for treatment of sling erosion, nerve injury, ureteral injury, groin/leg pain, and vaginal perforation. Obturator MUS result in shorter operative time, lower blood loss, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less OAB symptoms. Metaanalysis showed that postoperative OAB symptoms were more common in patients following retropubic slings (OR, 1.41; 95% CI, 1.01−1.98, $P = .046$). There was no difference between slings on metaanalysis of return for operating room for erosion or for retention. There were too few studies that examined subpopulations of stress-incontinent patients (eg, those with intrinsic sphincter deficiency or prior surgical failures) to allow metaanalysis.

In summary, for women considering a retropubic or transobturator MUS, we recommend either intervention for objective and subjective cure; the decision should be based on surgeon expertise accounting for AEs (Table 4).

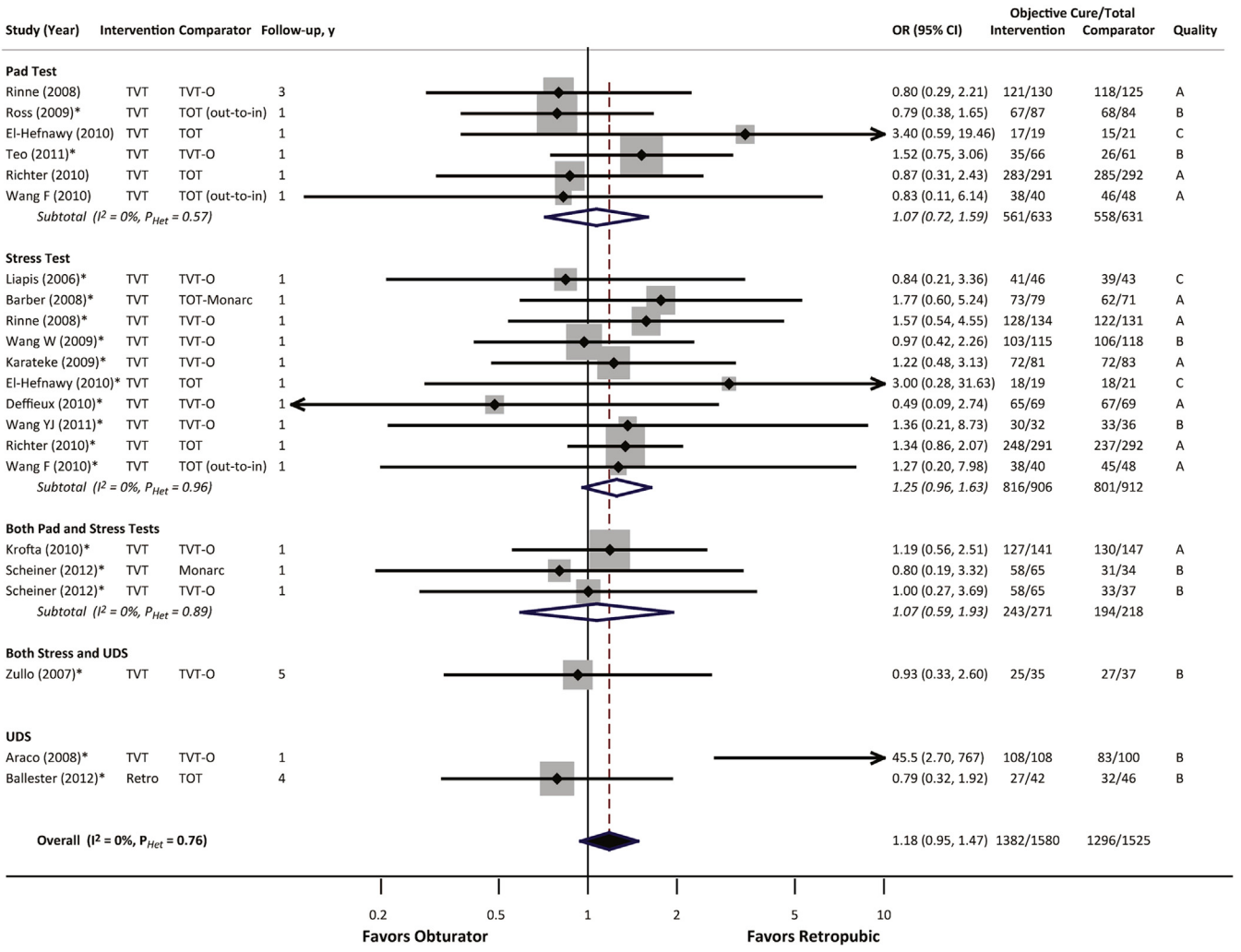
Retropubic MUS vs retropubic MUS

There was a limited number (2) of RCTs for this question, and moderate-quality evidence (Table 1) (Supplementary Table 5).[45,46] These studies each compared top-down passage (SPARC; AMS, Minnetonka, MN) to bottom-up passage (TVT). The evidence does not support a difference in outcomes between the retropubic slings studied. No studies reported quality-of-life or sexual function data.

Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

FIGURE 5
Metaanalysis for objective cure: retropubic (retro) vs obturator midurethral slings



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator; *UDS*, urodynamic study.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Obturator MUS vs obturator MUS

There have been 2 RCTs investigating this question, which provided low-quality evidence (Table 1) (Supplementary Table 6).[39,47] The evidence does not support a difference in outcomes between the routes of obturator slings studied.

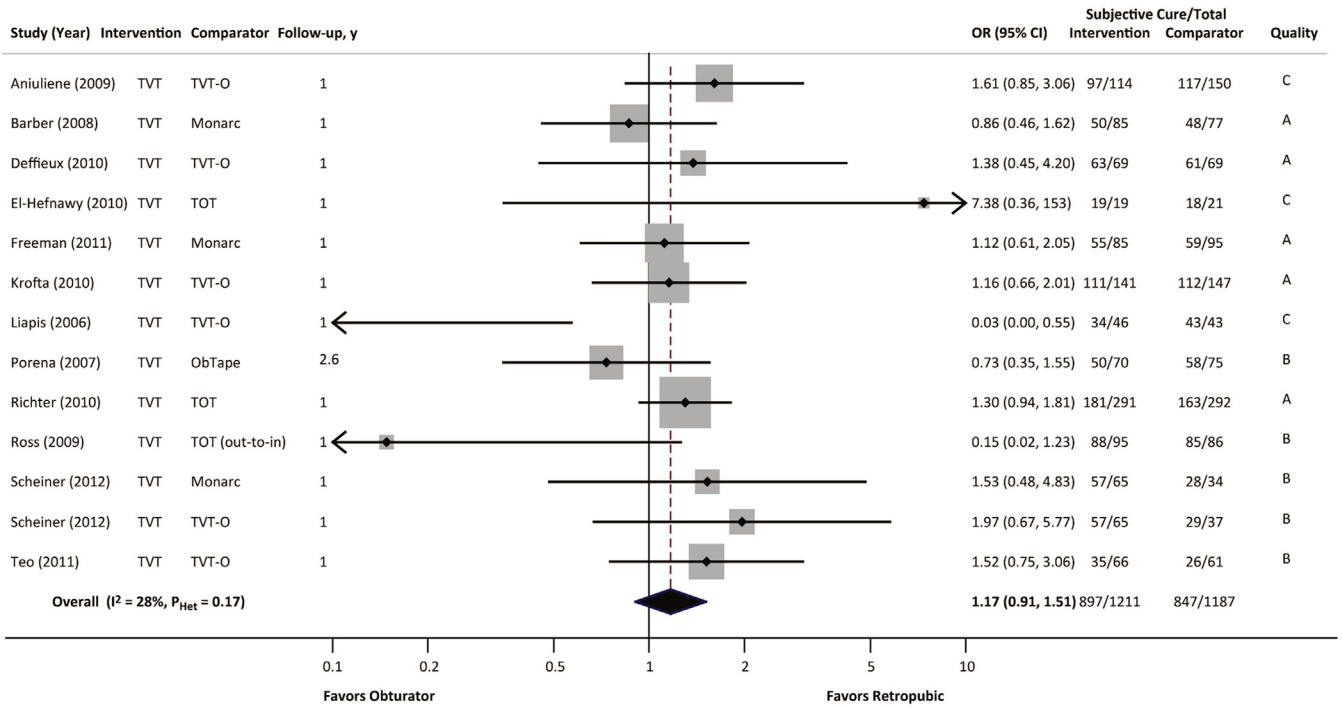
Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

Minislings vs any other slings

There were 15 RCTs providing data for this question, which represented 3-arm or 2-arm studies by original design (Table 1) (Supplementary Table 7).[43,48-56] The comparator arm of traditional full-length MUS was either an obturator or retropubic sling; no studies compared Burch urethropexy or pubovaginal slings to minislings. The majority of studies in this category used a TVT-Secur (Ethicon Gynecare, Cincinnati, OH) placed in either the "U" (similar to retropubic slings) or "H" (similar to obturator slings) configuration. While this product is no longer available in the United States, it was retained for this analysis because we thought that there was significant interest among physicians regarding this clinical question. By excluding studies with TVT-Secur (Ethicon Gynecare) from the analysis, a review and guideline on this question would not have been possible.

FIGURE 6
Metaanalysis for subjective cure: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Review of the evidence showed that both objective and subjective cure outcomes were improved with use of a full-length sling compared to a minisling.

Metaanalysis of objective cure outcomes significantly favored traditional full-length MUS, all of which happened to be an obturator sling (TVT-obturator), compared to minislings (OR, 4.16; 95% CI, 2.15–8.05) (Figure 8).

Results were similar for the metaanalysis of subjective cure outcomes (Figure 9). There were data included for both obturator and retropubic traditional MUS. Traditional MUS were found to be superior to minislings (OR, 2.65; 95% CI, 1.36–5.17).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies.

With respect to a comparison of AEs, the route (retropubic vs obturator) of the traditional full-length MUS is an important consideration (Table 3). For example, minislings have similar rates of postoperative OAB symptoms (5.4%) compared with obturator slings (5.3%), but somewhat lower rates than retropubic slings (6.9%). Exposure of the sling postoperatively is similar with either obturator slings (2.2%) or minislings (2.0%), but retropubic slings have somewhat lower rates than either (1.4%). Dyspareunia is rare with any type of sling, but is somewhat more common with a minisling (0.99%) than either a retropubic (<0.001%) or obturator (0.16%) sling. Minislings have the highest rate of urethral perforation (2.7% vs <1% for either retropubic or obturator), but the lowest rate of groin pain (0.62%) when compared to either route of MUS (1.5% for retropubic, 6.5% for obturator). Metaanalyses of the AE data failed to show a significant difference for OAB symptoms after surgery or return to the operating room for retention.

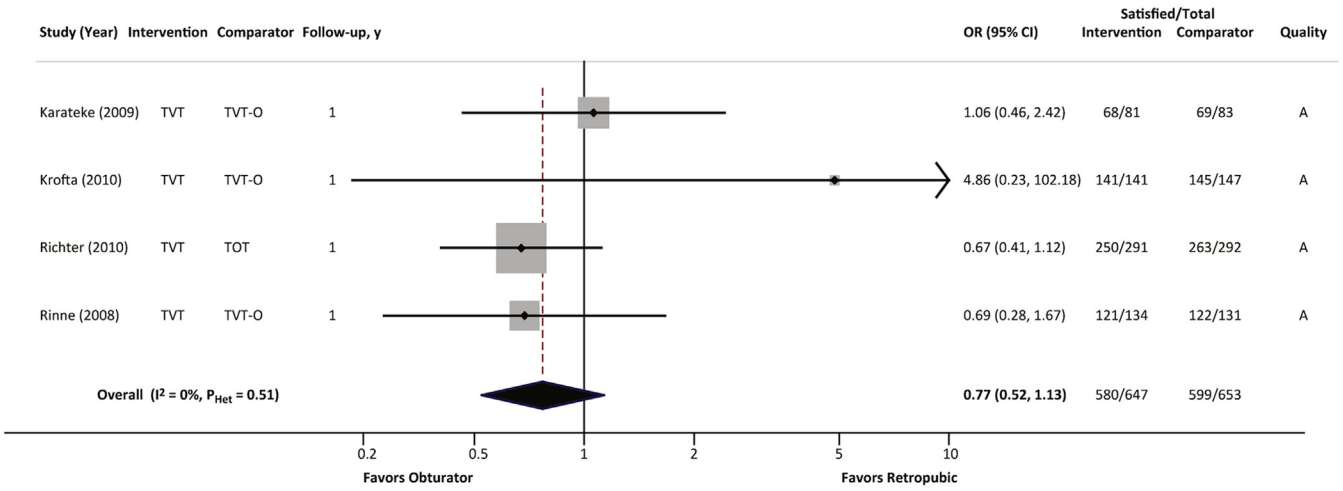
In summary, for women considering minislings or traditional full-length MUS, we recommend traditional full-length MUS to maximize cure rates (Table 4).

Comment

Surgical treatment of SUI has been well studied. MUS have become more common than pubovaginal sling procedures and Burch urethropexy for correction of SUI. In this systematic review we reviewed studies comparing MUS (retropubic, obturator, and minisling), pubovaginal slings, and Burch urethropexy for treatment of SUI in women. A large number of studies were available for review. In general, both the quality of study design and the inclusion of patient-centered outcomes have improved over time. We found low- to high-quality evidence permitting metaanalyses and development of clinical practice guidelines.

The best-studied comparison is for retropubic compared to obturator MUS, which included 21 separate studies. There appears to be little need to study

FIGURE 7
Metaanalysis for satisfaction: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

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this further for straightforward SUI unless surgical products change significantly. We found few reliable data for subpopulations; patients who have urethral sphincter weakness or a history of surgical failure, for example, are often analyzed together with primary surgical candidates with normal urethral function. Definitions of these conditions were highly variable, which meant we were not able to perform reliable analyses of these data. As these are challenging populations to treat clinically, they should be better studied in future work. There is 1 trial that exclusively enrolled women with intrinsic sphincter deficiency, defined either by maximum urethral closure pressure of <20 cm H_2O or leak point pressures of <60 cm H_2O.[39,76,77] While urodynamic stress incontinence 6 months postoperatively was more common in patients undergoing an obturator sling, objective cure rates based on pad test at 6 months, perioperative information, overall definition of "success," and sexual function data showed no difference between slings.[39,76,77] For subjective cure rates, the obturator sling was favored only on analysis of Incontinence Impact Questionnaire-7 total score data at 3 years' follow-up, with other markers and time periods for subjective cure measures not different between groups.[39,76,77] Rate of reoperation for SUI at 3 years of follow-up favored the retropubic sling in this population (18.3% of women in obturator sling group vs 1.2% of the women in the retropubic sling group on intention-to-treat analysis, $P<.001$) with a significantly shorter time to reoperation in the obturator group as well.[39,76,77]

Comparing MUS vs Burch urethropexy, there is moderate-quality evidence that either procedure provides equivalent subjective and objective cure rates. The benefits of a minimally invasive approach may be offset by the inclusion of concomitant procedures. For example, if other intraabdominal procedures are planned, this may mitigate the perioperative differences and AEs associated with Burch surgery compared to a MUS.

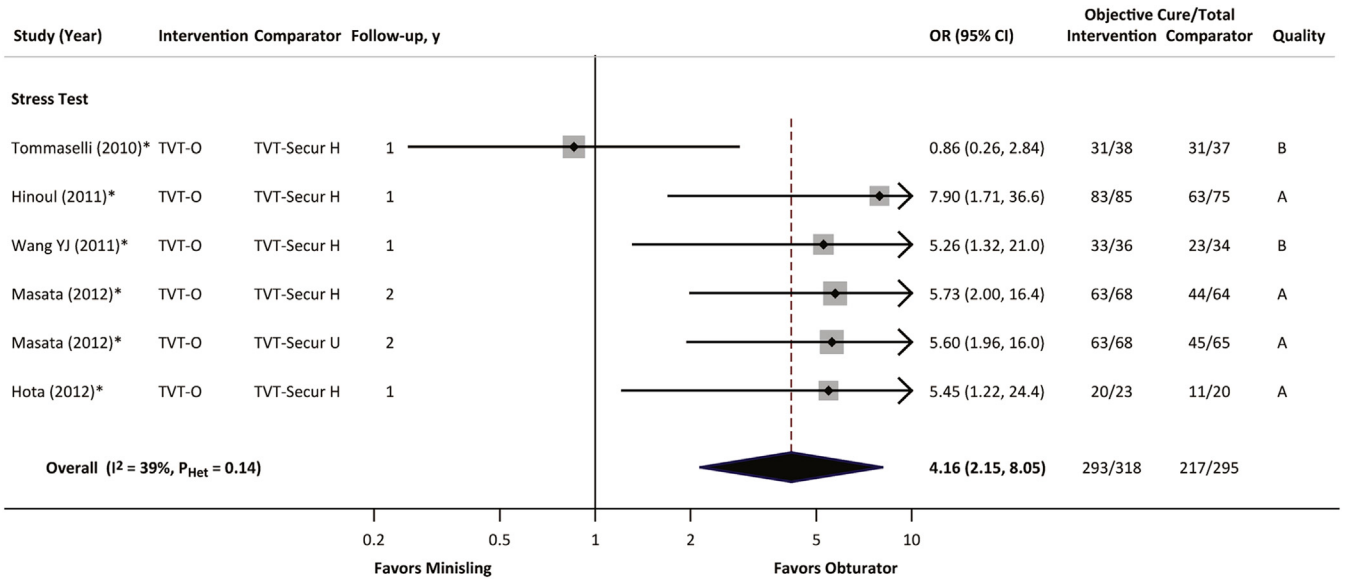
Only one study compared different types of pubovaginal slings to each other based on the type of sling material, and therefore we could not draw any conclusions on this question.[57]

We eliminated studies with <12 months' follow-up because of the robust body of literature on this topic (Table 1 presents length of follow-up for each study). Still, it is worthy to note that this is short-term from the perspective of a patient who desires lifelong cure. While challenging from an investigator standpoint, more studies with extended follow-up are needed.

One challenge in creation of clinical practice guidelines came when the importance of the various outcomes was weighed against each other. For example, should objective cure be more important overall than postsurgical sexual function? Many studies used composite success outcomes in an attempt to address this issue. The weight of these factors may also differ for surgeons and patients, and even between patients. For this reason, the clinical practice guideline statements provide detail to guide physician-patient counseling, which remains of paramount importance when planning surgery. Counseling also should address the impact of other concomitant procedures, such as hysterectomy and pelvic organ prolapse repair, in the decision-making process among the options for incontinence treatment.

Despite being the newest product on the market, the minislings had a large number of studies that met our inclusion criteria. Considering the interest in these slings, we thought it was merited to include TVT-Secur (Ethicon Gynecare)

FIGURE 8
Metaanalysis for objective cure: traditional midurethral sling (MUS) vs minisling



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Heb} χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

*Studies included in overall metaanalysis.

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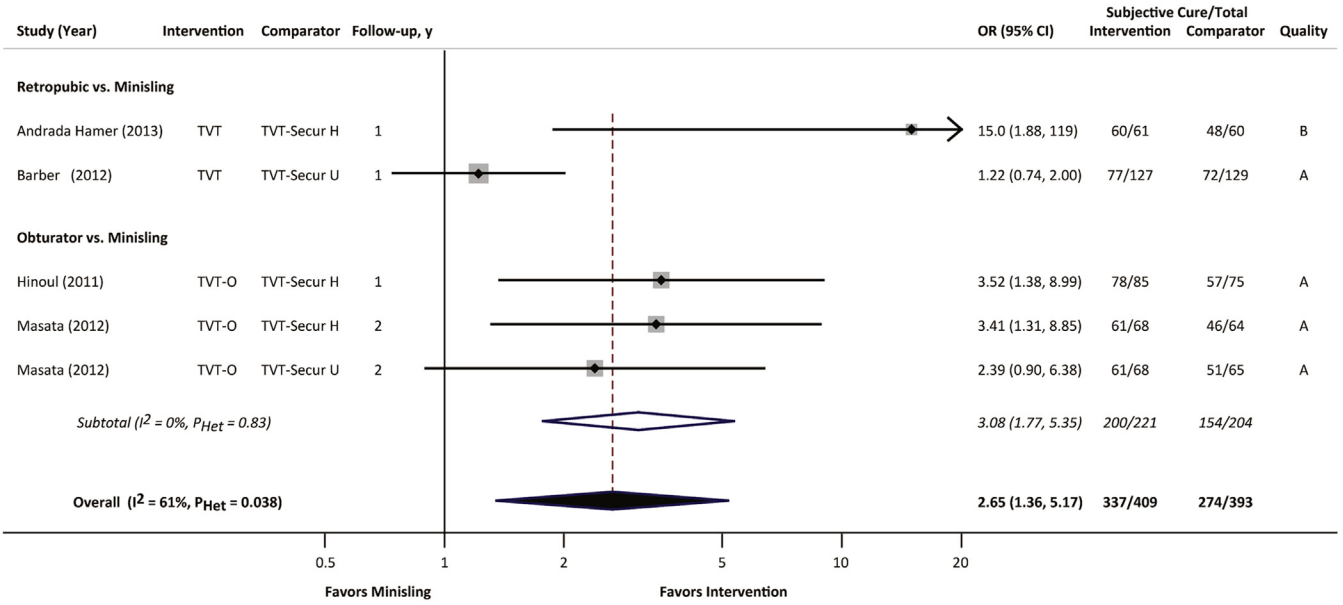
in our analysis although it has now been removed from the market. It should be noted that this is the most widely studied minisling, and the results of those studies and thus our review may not be generalizable to newer products. Further RCTs on these newer products are needed.

When choosing between surgical procedures, any surgeon must weigh the presumed benefits with the potential risks and AEs of these procedures. Balancing those against a specific patient's goals and desires is an important consideration for a diagnosis such as SUI in which treatment is elective based on degree of bother and quality-of-life impact. Additionally, surgeons should evaluate their own personal success and complication rates with the procedures and products they use, as these may differ from published rates. Whenever possible, physicians should counsel patients about the balance of both success rates and AEs for the various procedures discussed in this review. For example, some patients may tolerate some mild SUI to avoid any risk of obstructive OAB symptoms, while other patients would accept a high risk of needing to self-catheterize to avoid any SUI.

The strengths of this review include the large numbers of randomized clinical trials reviewed to provide data for the metaanalyses and clinical practice guidelines. Most of the randomized trials achieved their stated power and some studies reported long-term follow-up extending up to 5 years. Given the breadth of these data, we thought we could limit our review to studies with data at 12 months or longer, since patients and surgeons place higher value on long-term success rather than shorter-term rates. Our strict inclusion criteria, including the length of follow-up and the exclusion of meeting abstracts not submitted to the peer-review process, makes the included outcome data strong. There were also a large number of comparative cohort studies and observational studies to provide data on AEs. We were able to limit our collection to those studies with often >1000 patients to collect the most common problems rather than basing conclusions on rare, unusual events from smaller studies or case reports.

There are limitations to the study. Reporting of subpopulations of high interest to surgeons, including intrinsic sphincter deficiency and recurrent SUI, were variable and often not separated out from other patients in analyses, so we cannot draw conclusions about those populations. There was also high variability in reporting of numbers and types of complications in trials, making analyses of AE outcomes challenging. While many surgeons and patients are interested in information about postoperative symptoms such as urgency and de novo urgency, these symptoms were inconsistently reported, thus limiting their analysis. Additionally, data concerning need for retreatment were sparse and inconsistent, limiting our ability to draw any conclusions on this important question. Complications were assessed at different time intervals among different trials, and sometimes later trials reporting secondary analyses did not update longer-term AEs. The vast

FIGURE 9
Metaanalysis for subjective cure: traditional midurethral sling vs minisling



Forest plot subdivided by slings being compared with minisling. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

majority did not use a standard classification for complications such as the classification system of Dindo et al.[58] The length of follow-up for outcomes in most RCTs was up to 5 years but there was attrition as length of follow-up increased, which reduced the numbers of patients analyzed to determine long-term success rates for the slings or Burch urethropexy. Retropubic MUS, specifically TVT, is the best-studied procedure. There were few studies comparing different types of retropubic slings, obturator slings, or pubovaginal slings within those classifications, limiting our ability to comment on the best product/material.

In summary, this review supports the use of MUS for treatment of SUI compared to pubovaginal slings. The decision for retropubic vs obturator approaches to MUS may be based on the risks associated with each approach as no difference in effectiveness was found. The pubovaginal sling procedure is more effective than Burch urethropexy although, again, differences in surgical risks may guide the decision to utilize one approach over the other. Traditional MUS are significantly superior to minislings for cure outcomes. Overall, the evidence supporting use of MUS and pubovaginal slings is of high quality. These clinical practice guidelines provide an effective tool to assist in patient counseling and decision-making for the various surgical approaches to management of SUI. ■

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Appendix

SUPPLEMENTARY TABLE 1
Evidence profile for midurethral sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	9	994	1A (0), 4B (-1), 2B (-2), 2C (-2)	0	0	0	Moderate	No difference	Critical
Subjective cure	8	712	1A (-1), 2B (-1), 2B (-2), 3C (-2)	0	0	0	Moderate	No difference	Critical
Perioperative outcomes	9	964	1A (0), 4B (-1), 1B (-2), 3C (-2)	0	0	0	High	Favors midurethral	Variable
Quality of life	3	465	3B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	1	344	1B (-1)	NA	0	-1	Low	No difference	High
Total	10 separate studies								

Quality of overall evidence: moderate. Balance of benefits and harms: comparing midurethral slings (retropubic or obturator routes) to Burch (open or laparoscopic), there were no differences in objective or subjective cure, quality of life and sexual function outcomes. Metaanalyses for subjective and objective cure also showed no significant differences. There were not enough studies to perform a metaanalysis of subjective cure outcomes. Perioperative outcomes favored midurethral slings but long-term adverse event outcomes were less common with the Burch procedure. Metaanalysis of the adverse event outcomes where possible did not show a difference.

NA, not applicable.

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SUPPLEMENTARY TABLE 2
Evidence profile for PV sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	4	855	1A (0), 1B (-2), 1B (-1), 1C (-2)	0	0	0	High	Favors sling	Critical
Subjective cure	2	747	1A (0)	NA	0	0	High	Favors sling	Critical
Perioperative outcomes	3	819	1A (0), 1B (-1), 1C (-2)	0	0	0	High	Favors Burch	Variable
Quality of life	1	655	1A (0)	NA	0	0	High	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	4 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing PVS using fascia or synthetic material to Burch (open or laparoscopic) for SUI treatment, objective and subjective cure outcomes favor PVS. There was no difference seen for quality of life outcomes and no data regarding sexual functioning. Short-term (perioperative) and long-term adverse event outcomes favor Burch although some adverse events are less common with sling procedures.

NA, not applicable; *PVS*, pubovaginal slings; *SUI*, stress urinary incontinence.

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SUPPLEMENTARY TABLE 3

Evidence profile for pubovaginal sling vs midurethral sling

							Summary of findings		
Outcome	**No. studies**	**Total n**	**Methodological quality**	**Consistency**	**Directness**	**Other considerations**	**Evidence strength**	**Effect**	**Outcome importance**
Objective cure	3	233	1B (-1), 1B (-2), 1C(-2)	0	0	0	Low	No difference	Critical
Subjective cure	4	305	2B (-2), 1C (-2)	0	0	0	Very low	No difference	Critical
Perioperative outcomes	4	383	2B (-1), 2C (-2)	-1	0	0	Low	Favors midurethral	Variable
Quality of life	3	342	2B (-1), 1C (-2)	0	0	0	Low	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	5 separate studies								

Quality of overall evidence: low. Balance of benefits and harms: comparing PVS (fascia or synthetic material) to synthetic midurethral slings (only retropubic passage was studied), objective and subjective cure outcomes as well as quality of life and sexual function outcomes showed no differences. There were not enough studies available to perform a metaanalysis for objective cure outcomes, but a metaanalysis for subjective cure significantly favored midurethral slings. Both short-term (perioperative) and long-term adverse event data in general favored midurethral slings although metaanalysis did not show a difference for selected adverse-event outcomes.

NA, not applicable; *PVS*, pubovaginal slings.

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SUPPLEMENTARY TABLE 4

Evidence profile for retropubic vs obturator sling

							Summary of findings		
Outcome	**No. studies**	**Total n**	**Methodological quality**	**Consistency**	**Directness**	**Other considerations**	**Evidence strength**	**Effect**	**Outcome importance**
Objective cure	19	3354	7A (0), 6B (-1), 4B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Subjective cure	18	3186	6A (0), 2A (-1), 4B (-1), 2B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Perioperative outcomes	21	3811	8A (0), 10B (-1), 3C (-2)	-1	0	0	High	Most outcomes show no difference but wide range. For OR time, 10 studies show a difference and 8 favor obturator>retropubic. One study demonstrated that obturator sling patients were in hospital less time. For pain, 3 studies show a difference, 1 favoring retropubic and 2 favoring obturator.	Variable
Quality of life	15	2837	8A (0), 7B (-1)	0	0	0	High	No difference	Critical
Sexual functioning	10	2004	4A (0), 1A (-1), 4B (-2), 1B (-1)	0	0	0	High	No difference	High
Total	21 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing retropubic to obturator midurethral slings, there was no difference seen for objective cure, subjective cure, quality of life or sexual functioning outcomes. Metaanalysis favored retropubic slings for objective and subjective cure, although neither was significant. Metaanalysis for satisfaction favored obturator slings, but again was not significant. Adverse event data was variable across outcomes. Metaanalysis showed postoperative overactive bladder symptoms were more common with retropubic slings, but rates of retention and return to OR for erosion were similar.

OR, operating room.

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SUPPLEMENTARY TABLE 5

Evidence profile for retropubic vs retropubic sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	146	2B (-1)	0	0	0	Moderate	No difference	Critical
Subjective cure	1	84	1B (-1)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	2	146	2B (-1)	0	0	0	Moderate	No difference	Moderate
Quality of life	0	0	NA	NA	NA	NA	NA	NA	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	2 separate studies	146							

Quality of overall evidence: low. Balance of benefits and harms: comparing TVT (retropubic *bottom-up*) to SPARC (AMS, Minnetonka, MN) (retropubic *top-down*) in a population undergoing both prolapse repairs and anti-incontinence procedures, it is uncertain whether TVT is preferable to SPARC. There were few studies to analyze. Similar objective cure, perioperative event, and long-term adverse event rates (moderate quality evidence) and subjective cure rates (low quality evidence) are observed for TVT and SPARC. Data are insufficient to compare differences in postoperative QoL or sexual function. Adverse events could not be compared.

NA, not applicable; *QoL*, quality of life; *TVT*, tension-free vaginal tape.

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SUPPLEMENTARY TABLE 6

Evidence profile for obturator vs obturator sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Subjective cure	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	1	80	1B (-1)	NA	0	-1	NA	NA	Variable
Quality of life	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Sexual functioning	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	High
Total	2 studies								

Quality of overall evidence: low. Balance of benefits and harms: in 2 studies comparing routes of obturator sling passage (in-to-out vs out-to-in) for SUI, it is uncertain which route is preferable. Similar objective cure, subjective cure, quality of life and sexual functioning results were seen with low-quality evidence. Data are insufficient to compare short- or long-term adverse events.

NA, not applicable; *SUI*, stress urinary incontinence.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 7

Evidence profile for minisling vs other

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	15	1916	7A (0), 1B (-1), 4B (-2), 3C (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Subjective cure	9	1516	3A (0), 4A (-1), 1B (-1), 1B (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Perioperative outcomes	15	1916	7A (0), 5B (-1), 3C (-2)	-1	0	0	Moderate	For EBL, no difference in most studies. For catheter time favors TVT-O or no difference. For pain, favors minisling. Hospital time not different. OR time results mixed.	Variable
Quality of life	9	1467	7A (0), 2B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	3	708	1A (0), 2B (-1)	0	0	sparse	Moderate	No difference	High
Total	15 arms								

Quality of overall evidence: high. Balance of benefits and harms: Comparing traditional MUS (TVT or TVT-O) to the minislings (TVT-Secur U or H position, MiniArc), both objective and subjective cure outcomes strongly favored the traditional MUS, including on metaanalyses of both types of cure outcomes. No difference was seen for quality of life or sexual functioning outcomes. Adverse event outcomes were mixed and may depend on which MUS passage would be chosen as an alternative; metaanalysis of adverse-event data showed no difference. MiniArc; AMS, Minnetonka, MN; TVT-Secure; Ethicon Gynecare, Cincinnati, OH.

EBL, estimated blood loss; *MUS*, midurethral slings; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.